

107TH CONGRESS
1ST SESSION

H. R. 1862

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

IN THE HOUSE OF REPRESENTATIVES

MAY 16, 2001

Mr. BROWN of Ohio (for himself, Mrs. EMERSON, Mrs. THURMAN, Mr. PALLONE, Mr. BALDACCI, Mr. STUPAK, Mr. SHOWS, Mr. ALLEN, Ms. KAPTUR, Mr. SANDERS, and Mr. FRANK) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Greater Access to Af-
5 fordable Pharmaceuticals Act of 2001”.

6 **SEC. 2. FINDINGS; PURPOSES.**

7 (a) FINDINGS.—Congress finds that—

1 (1) prescription drug costs are increasing at an
2 alarming rate and are a major worry of American
3 families and senior citizens;

4 (2) enhancing competition between generic drug
5 manufacturers and brand-name manufacturers can
6 significantly reduce prescription drug costs for
7 American families;

8 (3) the pharmaceutical market has become in-
9 creasingly competitive during the last decade be-
10 cause of the increasing availability and accessibility
11 of generic pharmaceuticals, but competition must be
12 further stimulated and strengthened;

13 (4) the Federal Trade Commission has discov-
14 ered that there are increasing opportunities for drug
15 companies owning patents on brand-name drugs and
16 generic drug companies to enter into private finan-
17 cial deals in a manner that could restrain trade and
18 greatly reduce competition and increase prescription
19 drug costs for consumers;

20 (5) generic pharmaceuticals are approved by the
21 Food and Drug Administration on the basis of sci-
22 entific testing and other information establishing
23 that pharmaceuticals are therapeutically equivalent
24 to brand-name pharmaceuticals, ensuring consumers

1 a safe, efficacious, and cost-effective alternative to
2 brand-name innovator pharmaceuticals;

3 (6) the Congressional Budget Office estimates
4 that—

5 (A) the use of generic pharmaceuticals for
6 brand-name pharmaceuticals could save pur-
7 chasers of pharmaceuticals between
8 \$8,000,000,000 and \$10,000,000,000 each
9 year; and

10 (B) generic pharmaceuticals cost between
11 25 percent and 60 percent less than brand-
12 name pharmaceuticals, resulting in an esti-
13 mated average savings of \$15 to \$30 on each
14 prescription;

15 (7) generic pharmaceuticals are widely accepted
16 by consumers and the medical profession, as the
17 market share held by generic pharmaceuticals com-
18 pared to brand-name pharmaceuticals has more than
19 doubled during the last decade, from approximately
20 19 percent to 43 percent, according to the Congres-
21 sional Budget Office;

22 (8) expanding access to generic pharmaceuticals
23 can help consumers, especially senior citizens and
24 the uninsured, have access to more affordable pre-
25 scription drugs;

1 (9) Congress should ensure that measures are
2 taken to effectuate the amendments made by the
3 Drug Price Competition and Patent Term Restora-
4 tion Act of 1984 (98 Stat. 1585) (referred to in this
5 section as the “Hatch-Waxman Act”) to make ge-
6 neric drugs more accessible, and thus reduce health
7 care costs; and

8 (10) it would be in the public interest if patents
9 on drugs for which applications are approved under
10 section 505(c) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355(c)) were extended only
12 through the patent extension procedure provided
13 under the Hatch-Waxman Act rather than through
14 the attachment of riders to bills in Congress.

15 (b) PURPOSES.—The purposes of this Act are—

16 (1) to increase competition, thereby helping all
17 Americans, especially seniors and the uninsured, to
18 have access to more affordable medication; and

19 (2) to ensure fair marketplace practices and
20 deter pharmaceutical companies (including generic
21 companies) from engaging in anticompetitive action
22 or actions that tend to unfairly restrain trade.

1 **SEC. 3. ACCELERATED GENERIC DRUG COMPETITION.**

2 (a) IN GENERAL.—Section 505(j)(5) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is
4 amended—

5 (1) in subparagraph (B)(iv), by striking sub-
6 clause (II) and inserting the following:

7 “(II) the earlier of—

8 “(aa) the date of a final decision of a
9 court in an action described in clause (iii)
10 (from which no appeal can or has been
11 taken); or

12 “(bb) the date of a settlement order
13 or consent decree signed by a Federal
14 judge that enters a final judgment and in-
15 cludes a finding that the patents that are
16 the subject of the certification are invalid
17 or not infringed;”;

18 (2) by redesignating subparagraphs (C) and
19 (D) as subparagraphs (E) and (F), respectively; and

20 (3) by inserting after subparagraph (B) the fol-
21 lowing:

22 “(C) FORFEITURE OF 180-DAY PERIOD.—

23 “(i) IN GENERAL.—The 180-day pe-
24 riod described in subparagraph (B)(iv)
25 shall be forfeited by the previous applicant
26 and become available to the next applicant

1 submitting an application containing a cer-
2 tification described in paragraph
3 (2)(A)(vii)(IV) if—

4 “(I) the previous applicant fails
5 to market the drug within 90 days
6 after the date on which the approval
7 of the application for the drug is
8 made effective under subparagraph
9 (B)(iii);

10 “(II) the previous applicant with-
11 draws the application;

12 “(III) the previous applicant
13 amends the certification from a cer-
14 tification under subclause (IV) to a
15 certification under paragraph
16 (2)(A)(vii)(III), either voluntarily or
17 as a result of a settlement or defeat in
18 patent litigation;

19 “(IV) the previous applicant fails
20 to get tentative approval of the appli-
21 cation within 30 months after the
22 date on which the application is filed,
23 unless the failure is caused by—

24 “(aa) a change in the re-
25 quirements for tentative approval

1 of the application imposed after
2 the date on which the application
3 was filed; or

4 “(bb) other extraordinary or
5 unusual circumstances, as deter-
6 mined by the Secretary;

7 “(V) in a case in which, after the
8 date on which the previous application
9 was submitted under this subsection,
10 new patent information is submitted
11 for the drug under subsection (c)(2)
12 for a patent for which certification is
13 required under paragraph
14 (2)(A)(vii)(IV), the previous applicant
15 fails to challenge the patent that is
16 the subject of the information within
17 60 days after the date on which the
18 patent information is submitted; or

19 “(VI) the previous applicant is
20 determined by the Secretary, after a
21 fair and sufficient hearing and in con-
22 sultation with the Federal Trade
23 Commission, to have engaged in anti-
24 competitive or collusive conduct, or
25 any other conduct intended to unfairly

1 monopolize the commercial manufac-
2 turing of the drug of the application.

3 “(ii) AVAILABILITY.—The 180-day pe-
4 riod described in subparagraph (B)(iv)
5 shall be available only to—

6 “(I) the previous applicant sub-
7 mitting an application for a drug
8 under this subsection containing a
9 certification described in paragraph
10 (2)(A)(vii)(IV) with respect to any
11 patent; or

12 “(II) under clause (i), the next
13 applicant submitting an application
14 for a drug under this subsection con-
15 taining such a certification with re-
16 spect to any patent;

17 even if an application has been submitted
18 for the drug under this subsection con-
19 taining such a certification with respect to
20 a different patent.

21 “(iii) APPLICABILITY.—The 180-day
22 period described in subparagraph (B)(iv)
23 shall apply only if—

1 “(I) the application contains a
 2 certification described in paragraph
 3 (2)(A)(vii)(IV); and

4 “(II) an action is brought for in-
 5 fringement of a patent that is the
 6 subject of the certification or the ap-
 7 plicant brings an action (not later
 8 than 50 days after the date on which
 9 the notice provided under paragraph
 10 (2)(B)(ii) was received), against the
 11 holder of the approved application for
 12 the listed drug.”.

13 (b) EFFECTIVE DATE.—The amendment made by
 14 this section shall be effective only with respect to an appli-
 15 cation filed under section 505(j) of the Federal Food,
 16 Drug, and Cosmetic Act (21 U.S.C. 355(j)) for a listed
 17 drug for which no certification under section
 18 505(j)(2)(A)(vii)(IV) of that Act was made before the date
 19 of enactment of this Act.

20 **SEC. 4. BIOEQUIVALENCE TESTING METHODS.**

21 Section 505(j)(8)(B) of the Federal Food, Drug, and
 22 Cosmetic Act (21 U.S.C. 355(j)(8)(B)) is amended—

- 23 (1) in clause (i), by striking “or” at the end;
 24 (2) in clause (ii), by striking the period at the
 25 end and inserting “; or”; and

1 (3) by adding at the end the following:

2 “(iii)(I) clauses (i) and (ii) are not applica-
3 ble, as determined by the Secretary;

4 “(II) the effects of the drug and the listed
5 drug do not show a significant difference based
6 on tests (other than tests that assess rate and
7 extent of absorption), including—

8 “(aa) a bioequivalence study with a
9 pharmacodynamic endpoint;

10 “(bb) a bioequivalence study with a
11 clinical endpoint;

12 “(cc) in vitro methods; or

13 “(dd) any other methodology that
14 demonstrates that no significant dif-
15 ferences in therapeutic effects of active in-
16 gredients are expected; and

17 “(III) limited confirmatory studies to sup-
18 plement the bioequivalence testing are consid-
19 ered necessary by the Secretary.”.

20 **SEC. 5. CITIZEN PETITIONS.**

21 Section 505(j)(5) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by sec-
23 tion 3(a)) is amended by inserting after subparagraph (C)
24 the following:

25 “(D) CITIZEN PETITIONS.—

1 “(i) IN GENERAL.—Notwithstanding
2 any other provision of law, any petition
3 submitted under section 10.30 of title 21,
4 Code of Federal Regulations (or any suc-
5 cessor regulation), shall include a state-
6 ment that to the best knowledge and belief
7 of the petitioner, the petition—

8 “(I) includes all information and
9 views on which the petitioner relies;

10 “(II) is well grounded in fact and
11 is warranted by law (including regula-
12 tions);

13 “(III) is not submitted for any
14 improper purpose, such as to harass
15 or cause unnecessary delay;

16 “(IV) does not contain a materi-
17 ally false, misleading, or fraudulent
18 statement that the petitioner has
19 knowingly and willingly included; and

20 “(V) includes all representative
21 data and information known to the
22 petitioner that is favorable or unfavor-
23 able to the petition.

24 “(ii) APPLICABILITY OF CRIMINAL
25 PROVISION.—Section 1001 of title 18,

1 United States Code, shall apply to a per-
2 son that submits a petition under section
3 10.30 of title 21, Code of Federal Regula-
4 tions (or any successor regulation).

5 “(iii) INVESTIGATIONS.—

6 “(I) IN GENERAL.—The Federal
7 Trade Commission shall investigate,
8 on receipt of a complaint or upon its
9 own initiative, any petition submitted
10 under section 10.30 of title 21, Code
11 of Federal Regulations (or any suc-
12 cessor regulation), that may have been
13 submitted for an improper purpose,
14 such as to delay competition or agen-
15 cy action.

16 “(II) REFERRAL.—If the Com-
17 mission finds that a petitioner has en-
18 gaged in conduct that may be illegal,
19 the Commission shall refer the peti-
20 tion to the Antitrust Division of the
21 Department of Justice for further ac-
22 tion.

23 “(iv) NOTICE OF RECEIPT OF CONSID-
24 ERATION.—

1 “(I) IN GENERAL.—A person
2 that submits a petition under section
3 10.30 of title 21, Code of Federal
4 Regulations (or any successor regula-
5 tion), shall provide a written notice to
6 the Federal Trade Commission if the
7 person receives any consideration for
8 submitting the petition.

9 “(II) A notice under subclause
10 (I) shall include—

11 “(aa) the name of the per-
12 son or entity that provided the
13 consideration;

14 “(bb) the dollar value of the
15 consideration, if provided in cash,
16 or a description of such consider-
17 ation;

18 “(cc) the date on which the
19 consideration was provided; and

20 “(dd) any other information
21 that the Commission requires to
22 be disclosed.”.

23 **SEC. 6. PATENT CERTIFICATION.**

24 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
25 tion 505(j)(5) of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 355(j)(5)) (as amended by section 3(a)(2))
2 is amended—

3 (1) in subparagraph (B), by striking clause (iii)
4 and inserting the following:

5 “(iii) CERTIFICATION THAT PATENT
6 IS INVALID OR WILL NOT BE INFRINGED.—

7 “(I) IN GENERAL.—Except as
8 provided in subclauses (II) and (III),
9 if the applicant made a certification
10 described in paragraph
11 (2)(A)(vii)(IV), the approval shall be
12 made effective on the expiration of 45
13 days after the date on which the no-
14 tice provided under paragraph
15 (2)(B)(ii) was received.

16 “(II) ACTION FOR PATENT IN-
17 FRINGEMENT.—If an action is
18 brought for infringement of a patent
19 that is the subject of the certification
20 before the expiration of the 45-day pe-
21 riod beginning on the date on which
22 the notice provided under paragraph
23 (2)(B)(ii) was received, the approval
24 shall be made effective on the expira-
25 tion of the 45-day period unless the

1 court grants a preliminary injunction
2 prohibiting the applicant from engag-
3 ing in the commercial manufacture or
4 sale of the drug until the court de-
5 cides the issues of patent validity and
6 infringement.

7 “(III) PATENT INVALID OR NOT
8 INFRINGED.—If the court decides that
9 the patent is invalid or was not in-
10 fringed, the approval shall be made ef-
11 fective on the date of the court deci-
12 sion.

13 “(IV) PATENT INFRINGED.—If
14 the court decides that the patent was
15 infringed, the approval shall be made
16 effective on such date as the court or-
17 ders under section 271(e)(4)(A) of
18 title 35, United States Code.

19 “(V) PROCEDURE.—In an action
20 described in subclause (II)—

21 “(aa) each of the parties
22 shall reasonably cooperate in ex-
23 pediting the action;

24 “(bb) until the expiration of
25 45 days after the date the notice

provided under paragraph
(2)(B)(i) was received, no civil
action may be brought under sec-
tion 2201 of title 28, United
States Code, for a declaratory
judgment with respect to the pat-
ent, except as provided in sub-
paragraph (H); and

“(cc) any such civil action
shall be brought in the judicial
district in which the defendant
has its principal place of business
or a regular and established place
of business.”; and

(2) by adding at the end the following:

“(G) CIVIL ACTION FOR DECLARATORY
JUDGMENT.—A person that files an abbreviated
application for a new drug under this para-
graph may bring a civil action against the hold-
er of an approved application for a listed drug
for a declaratory judgment to determine wheth-
er the patent that claims the listed drug or a
method of using the drug is invalid or will not
be infringed.

1 “(H) CIVIL ACTION TO DETERMINE LEGAL
2 STATUS.—Notwithstanding any other provision
3 of law, if information on a patent for a listed
4 drug has been published under subsection (c)(2)
5 for at least 1 year after the date on which an
6 abbreviated application for approval of a new
7 drug was filed under this subsection in relation
8 to the listed drug, the person that filed the ab-
9 breviated application or the holder of the ap-
10 proved application for the listed drug may im-
11 mediately bring a civil action to determine the
12 legal status of the patent for the listed drug.”.

13 (b) NEW DRUG APPLICATIONS.—Section 505(c)(3)
14 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 355(c)(3)) is amended by striking subparagraph (C) and
16 inserting the following:

17 “(C) CERTIFICATION THAT PATENT IS IN-
18 VALID OR WILL NOT BE INFRINGED.—

19 “(i) IN GENERAL.—Except as pro-
20 vided in clauses (ii) and (iii), if the appli-
21 cant made a certification described in sub-
22 section (b)(2)(A)(iv), the approval shall be
23 made effective on the expiration of 45 days
24 after the date on which the notice provided
25 under subsection (b)(3)(B) was received.

1 “(ii) ACTION BROUGHT BEFORE EXPI-
2 RATION OF 45 DAYS.—If an action is
3 brought for infringement of a patent that
4 is the subject of the certification before the
5 expiration of the 45-day period beginning
6 on the date the notice provided under sub-
7 section (b)(3)(B) was received, the ap-
8 proval shall be made effective on the expi-
9 ration of the 45-day period unless the
10 court grants a preliminary injunction pro-
11 hibiting the applicant from engaging in the
12 commercial manufacture or sale of the
13 drug until the court decides the issues of
14 patent validity and infringement.

15 “(iii) PATENT INVALID OR NOT IN-
16 FRINGED.—If the court decides that the
17 patent is invalid or not infringed, the ap-
18 proval shall be made effective on the date
19 of the court decision.

20 “(iv) PATENT INFRINGED.—If the
21 court decides that the patent has been in-
22 fringed, the approval may be made effec-
23 tive on such date as the court orders under
24 section 271(e)(4)(A) of title 35, United
25 States Code.

1 “(v) PROCEDURE.—In an action de-
2 scribed in clause (ii)—

3 “(I) each of the parties shall rea-
4 sonably cooperate in expediting the
5 action;

6 “(II) until the expiration of 45
7 days after the date the notice provided
8 under subsection (b)(3)(B) was re-
9 ceived, no civil action may be brought
10 under section 2201 of title 28, United
11 States Code, for a declaratory judg-
12 ment with respect to the patent, ex-
13 cept as provided in subsection
14 (j)(5)(H); and

15 “(III) any such civil action shall
16 be brought in the judicial district
17 where the defendant has its principal
18 place of business or a regular and es-
19 tablished place of business.”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section shall not apply to an application submitted
22 under section 505 of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 355) before the date of enactment
24 of this Act.

1 **SEC. 7. PATENT INFORMATION.**

2 Section 505 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 355) is amended—

4 (1) in subsection (b), by striking “(b)(1) Any
5 person” and all that follows through paragraph (1)
6 and inserting the following:

7 “(b) APPLICATIONS.—

8 “(1) IN GENERAL.—

9 “(A) FILING.—Any person may file with
10 the Secretary an application with respect to any
11 drug subject to subsection (a).

12 “(B) CONTENTS.—A person that files an
13 application shall submit to the Secretary as a
14 part of the application with respect to a drug—

15 “(i) full reports of investigations that
16 have been made to show whether or not
17 such drug is safe for use and whether the
18 drug is effective in use;

19 “(ii) a full list of the articles used as
20 components of the drug;

21 “(iii) a full statement of the composi-
22 tion of the drug;

23 “(iv) a full description of the methods
24 used in, and the facilities and controls
25 used for, the manufacture, processing, and
26 packing of the drug;

1 “(v) such samples of the drug and of
2 the articles used as components of the
3 drug as the Secretary may require; and

4 “(vi) specimens of the labeling pro-
5 posed to be used for the drug.

6 “(C) PATENT INFORMATION.—

7 “(i) IN GENERAL.—The applicant
8 shall file with the application the patent
9 number and expiration date of any patent
10 that claims a drug or method of using a
11 drug and with respect to which a claim of
12 patent infringement could reasonably be
13 asserted if a person not licensed by the
14 owner engaged in the manufacture, use, or
15 sale of the drug for which the applicant
16 submitted the application.

17 “(ii) AMENDMENT OF APPLICATION.—
18 If an application is filed with respect to a
19 drug and a patent as described in clause
20 (i) is issued after the filing date but before
21 approval of the application, the applicant
22 shall amend the application to include the
23 information required by clause (i).

24 “(iii) PUBLICATION OF INFORMA-
25 TION.—On approval of the application, the

1 Secretary shall publish information sub-
2 mitted under clauses (i) and (ii).

3 “(D) GUIDANCE.—The Secretary shall, in
4 consultation with the Director of the National
5 Institutes of Health and with representatives of
6 the drug manufacturing industry, review and
7 develop guidance, as appropriate, on the inclu-
8 sion of women and minorities in clinical trials
9 required by subparagraph (B)(i).”; and
10 (2) in paragraph (2)(A)—

11 (A) by striking “which claims” the first
12 place it appears and all that follows through
13 “subsection and”; and

14 (B) by striking “subsection (c)—” and in-
15 serting “and with respect to which a claim of
16 patent infringement could reasonably be as-
17 serted if a person not licensed by the owner en-
18 gaged in the manufacture, use, or sale of the
19 drug for which the investigations were con-
20 ducted—”;

21 (3) in the first sentence of subsection (c)(2)—

22 (A) by inserting “such patent information”
23 after “shall file”; and

24 (B) by striking “Secretary,” and all that
25 follows and inserting “Secretary.”;

1 (4) in subsection (j)(2)(vii), by striking “which
2 claims the listed drug” and all that follows through
3 “under this subsection and” and inserting “for the
4 listed drug referred to in clause (i)”; and

5 (5) by adding at the end the following:

6 “(o) PATENT INFORMATION.—

7 “(1) APPLICABILITY.—This subsection applies
8 to a holder of an approved application under sub-
9 section (c) that files a patent—

10 “(A) that claims, with regard to a drug of
11 the application, a drug or method of using a
12 drug; and

13 “(B) for which a claim of patent infringe-
14 ment could reasonably be asserted if a person
15 not licensed by the owner engaged in the manu-
16 facture, use, or sale of the drug, after the date
17 of approval of the application.

18 “(2) CERTIFICATION.—A holder of a patent de-
19 scribed in paragraph (1) shall—

20 “(A) inform the Secretary of the filing of
21 the patent; and

22 “(B) certify that the information is a com-
23 plete and accurate listing of all such patents.

1 “(3) SECRETARY.—The Secretary shall list the
2 information provided under paragraph (2) in accord-
3 ance with subsection (j)(7).”.

4 **SEC. 8. REPORT.**

5 (a) IN GENERAL.—Not later than the date that is
6 5 years after the date of enactment of this Act, the Fed-
7 eral Trade Commission shall submit to Congress a report
8 describing the extent to which implementation of the
9 amendments made by this Act—

10 (1) has enabled products to come to market in
11 a fair and expeditious manner, consistent with the
12 rights of patent owners under intellectual property
13 law; and

14 (2) has promoted lower prices of drugs and
15 greater access to drugs through price competition.

16 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
17 authorized to be appropriated to carry out this section
18 \$5,000,000.

○